WOMEN'S HEALTH IN SPORTS AND EXERCISE

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PARTICIPATING INSTITUTES AND CENTERS (ICs):
National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIAMS
(http://www.niams.nih.gov/)
National Institute of Child Health and Human Development, NICHD
(http://www.nichd.nih.gov/)
Office of Research on Women's Health, ORWH
(http://www4.od.nih.gov/orwh/)

THIS PA CONTAINS THE FOLLOWING INFORMATION

PURPOSE OF THIS PA

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institute of Child Health and Human Development (NICHD) and the Office of Research on Women's Health (ORWH) encourage investigator-initiated research grant applications to study women's health in sports and exercise. The purpose of this Program Announcement (PA) is to stimulate and foster a wide range of basic, translational and patient-oriented clinical studies.

Improvement in our basic knowledge of the pathophysiology of sports injuries in women will help to solve the puzzle of why female athletes are more susceptible to certain types of injury. In addition, translational studies will be helpful in developing optimal prevention, rehabilitation and training strategies for injuries and overuse syndromes in the female athlete throughout the life spectrum. This pathophysiology may also be applicable to women with disabilities, as compensation for disability often includes some athletic activity.

RESEARCH OBJECTIVES

It is well known that enhanced physical activities have numerous beneficial health effects during adult years, such as a reduction in morbidity and mortality from diseases of several body systems (e.g., cardiovascular disease). An unfortunate consequence of physical fitness and sports participation is the development of injuries. In the United States, organized athletic programs involve at least 20 million children and adolescents each year (Tofler I, et al, N Engl J Med 1996 Jul 25;335:281-283). The possibility of a high school athlete being injured during a season ranges from a low of 21%, to a high of 81%, in football (Women's Health in Sports and Exercise, AAOS 2001). Mueller estimates that a median injury rate of 50% would result in >3 million high school sports injuries per year. Most athletic injuries are not accidents and are preventable.

With increased participation of women in sports activities, there has been a concomitant increase in sports injuries and overuse syndromes in women. Women participating in the same sports as men generally have the same type of injuries as their male counterparts (Arendt E, et al, Am J Sports Med 1995 Nov-Dec; 23(6):694-701). Anatomical and physiological considerations give female participants certain advantages, some disadvantages, and result in several unique injury risks and conditions, as compared to their male counterparts. In particular, female athletes appear to be 2-8 times more likely to sustain a knee or ankle injury than their male counterparts. This has been related to anatomical differences, neuromuscular differences, and to the possibility that estrogen receptors, normally present in ligaments, may serve as an intrinsic risk factor to ligamentous injury. While preliminary studies have shown that the results of reconstruction of the knee's anterior cruciate ligament, for example, may not be gender-dependent, little is known about optimal treatments and rehabilitation strategies for common female athletic injuries.

Other musculoskeletal problems also are more common in the female athlete. These include scoliosis in the spine, patellofemoral problems, bunions, and increased pronation in the foot. Another potential issue related to the foot is the fact that most women's athletic shoes are designed for men and have been scaled down, but not adapted to the shape of a woman's foot.

Following the work of Cann and associates, the phrase "the female athletic triad" was coined to describe the complex interplay of disordered eating, menstrual irregularity, and osteoporosis seen in the female athlete (Cann DE, et al, JAMA 1984 Feb 3;251(5):626-9). It is not known whether the loss in bone mineral density at a young age will lead to premature fracture, but the incidence of stress fractures in amenorrheic athletes is increasing (The Female Athlete, AAOS 1997).

The current PA indicates the NIAMS's, NICHD's and ORWH's continued interest in fitness, sports-related musculoskeletal injuries, and women's health in sports and exercise. The NICHD conducts and supports biomedical and behavioral research and research training in exercise for individuals with physical disabilities. It is a direct outgrowth of a NIAMS and American Academy of Orthopaedic Surgeons (AAOS) sponsored workshop on the status and future research directions of Women's Health in Sports and Exercise, held in June 1999. The purpose of the workshop was to explore ways to encourage physical activity while trying to understand what can be done to prevent activity-related injuries. To accomplish these aims, a multi-disciplinary panel of basic and clinical scientists was assembled to define current knowledge and to identify future cross-cutting research directions. A more detailed description of the proceedings and suggested research topics can be found in Women's Health in Sport and Exercise, which can be obtained from the American Academy of Orthopaedic Surgeons, 6300 North River Road, Rosemont, Illinois 60018 or at the following URL address: http://www3.aaos.org/product/prt_item.cfm?code=02516.

Through the use of this PA, the NIAMS, NICHD and ORWH anticipate the receipt of a broad range of applications targeted, but not limited, to the following areas related to women's health in sports and fitness.

A. Epidemiologic Issues

Collect epidemiologic data on women's athletic injuries and overuse syndromes, including injury data, exposure data, demographic data, equipment information, injury history, playing experience, and data on women with disabilities who sustain common injuries that are normally sports-related.

Identify risk factors for common musculoskeletal injuries.

Clarify the anatomic, physiologic, and psychological effects of sports participation during the adolescent years. Determine whether injuries are more likely at this time and if so, determine their long-term effects.

Clarify the epidemiologic data on stress fractures, exploring the effects of (1) age, (2) gender, (3) skeletal status, (4) hormonal stress, (5) nutrition, (6) training techniques, and (7) sport specificity.

Examine the value of single sport versus multiple sports participation by young women, assessing the effect of such on (1) injury rates, (2) continued participation in fitness activities as an adult, (3) levels of fitness, and coping skills (psychological well-being).

Characterize the natural history of joint injury and subsequent degenerative joint disease, and determine if treatment strategies alter these results. Determine the effect of treatment and preventive strategies in women with disabilities.

Establish prospective epidemiologic studies to define risk factors for exercise-related musculoskeletal problems.

Determine the long-term effects of disability on the musculoskeletal system, particularly in women who participate in sports and recreational activities.

B. Neuromuscular Issues

Investigate neuromuscular control mechanisms used by the central nervous system to control joint musculature and stability in normal and injured states.

Study the patterns of movement for walking, running, and athletic maneuvers for important variables associated with respect to age and level of experience.

Determine the optimal patterns of neural activation within a given sport activity.

Determine whether motor patterns in women are inherent or are driven by experience.

Determine whether motor activation patterns change with different stages of development, e.g., prepubescent, adolescent, early adult, elderly.

Further define at-risk injury positions for women's sports and develop strategies to prevent these at-risk situations and to respond more appropriately when they occur.

Determine if there are gender-specific differences in movement patterns and if such differences affect injury risks. If such patterns are discovered, are they alterable?

Identify differences in proprioception and neuromuscular control and how these relate to injuries and injury prevention techniques.

Identify and characterize motor control strategies/movement patterns and relate them to risks of acute and chronic injuries.

Identify possible differences in neuromuscular control in women with disabilities, as compared with able-bodied women.

C. Basic Science Issues

Identify specific neuromuscular proprioceptive and motor control factors associated with ACL injury.

Elucidate the appropriate dose-response relationship of physical activity to injury, across the life spectrum (pre-adolescent, adolescent, young adult, and aging adult).

Assess the relationship of body composition and performance in sports and physical activity.

Assess the relationship between performance and nutritional intake in the female athlete.

Clarify why females are more vulnerable to overuse syndromes.

Elucidate the effects of cyclical hormones on musculoskeletal soft tissues, especially ligaments, and their relationship to injury.

Clarify the role and effects of exercise and competition during pregnancy.

Evaluate the role of nutritional and hormonal status on responses to exercise training in women throughout the lifespan.

Elucidate the role of intense physical activities on normal bone metabolism throughout the life spectrum. This should lead to the development of optimal training methods and adjuvant therapies to maximize bone mineral density.

Assess if women with disabilities, who are compensating in order to achieve or maintain previously acquired or potential functional levels, are also susceptible to certain sport or recreational injuries.

D. Coaching/Training/Equipment Issues

Continue to investigate the multitude of physiological, biochemical, and psycho-social responses to training during pregnancy.

Determine the optimal resistance training programs for the most favorable adaptations and benefits across the life spectrum.

Establish guidelines for medical clearance and continued athletic participation.

Better understand the roles of sports floor surfaces and foot-surface interfaces on injury rates. Can gender-specific shoe wear or sports surfaces or a combination of both improve safety?

Better understand the role(s) of sport-specific equipment and protective devices in enhancing athletic safety and performance. Is such equipment gender specific?

Develop optimal training methods for young female athletes to improve fundamental motor skills.

E. Surveillance/Patient-Oriented Research Issues

Conduct randomized clinical trials and population-based investigations to more fully specify the types, modes, amounts, intensities, and patterns of physical activity that are necessary to promote health and specific physiologic and metabolic adaptations and to facilitate recovery/rehabilitation from disease and injury.

Improve surveillance systems to (1) monitor population levels and trends of physical activity and fitness, especially for the current consensus public health recommendations for physical activity, and (2) document exercise-related health problems such as musculoskeletal injuries and sudden death associated with exercise.

Conduct long-term trials of physical activity interventions across the life spectrum, to evaluate their long-term effects on activity behavior and health.

Develop optimal prevention, intervention and treatment strategies for each dimension of the female athletic triad. Develop clinical guidelines for screening, prevention, and treatment of the female athletic triad.

Design prospective studies that relate prevention strategies to modifiable risk factors or to modifiable injury mechanisms.

Develop prospective studies to identify females at risk for ACL injuries, and to better understand the factors that predispose to this injury.

Develop optimal rehabilitation techniques for the treatment and prevention of musculoskeletal injuries and overuse syndromes in female athletes.

F. Social/Psychological Issues

Identify factors that motivate girls' participation in sports and exercise, as well as factors that lead to attrition from or exercise participation.

Define and develop strategies to overcome socioeconomic, ethnic, and/or cultural barriers to girls participating in sports and physical activity.

Identify (1) psychological risk factors for injury; (2) short and long-term effects of injury; and (3) determine appropriate intervention in the management of emotional issues after injury, in the female athlete.

Investigate factors that facilitate involvement as well as barriers to participation in sports and physical activity for women throughout the life spectrum.

Investigate the biopsychosocial factors underlying the causes of the female athletic triad.

MECHANISM(S) OF SUPPORT

This PA will use the NIH research project grant (R01) award mechanism(s). As an applicant, you will be solely responsible for planning, directing, and executing the proposed project. The total project period for an application submitted in response to this PA may not exceed 5 years.

This PA uses just-in-time concepts. It also uses the modular as well as the non-modular budgeting formats (see http://grants.nih.gov/grants/funding/modular/modular.htm). Specifically, if you are submitting an application with direct costs in each year of $250,000 or less, use the modular format. Otherwise follow the instructions for non-modular research grant applications.

ELIGIBLE INSTITUTIONS

You may submit (an) application(s) if your institution has any of the following characteristics:

o For-profit or non-profit organizations
o Public or private institutions, such as universities, colleges, hospitals, and laboratories
o Units of State and local governments
o Eligible agencies of the Federal government
o Domestic or foreign
o Faith-based organizations

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

WHERE TO SEND INQUIRIES

We encourage your inquiries concerning this PA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into two areas: scientific/research, and financial or grants management issues:

o Direct your questions about scientific/research issues to:

James S. Panagis, MD, MPH
Director, Orthopaedics Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Building 45, Room 5AS-37K, MSC 6500
Bethesda, MD 20892
Telephone: (301) 594-5055

FAX: (301) 480-4543
Email: jp149d@nih.gov

Carol Sheredos, PT, MA
Program Support Specialist
National Center for Medical and Rehabilitation Research
National Institute of Child Health and Human Development
6100 Executive Blvd., Room 2A03
Bethesda, MD 20892
Telephone:(301) 402-2242
FAX:(301) 402-0832
Email: sheredc@mail.nih.gov

o Direct your questions about financial or grants management matters to:

Melinda Nelson
Grants Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-49F, MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-3535
FAX: (301) 480-5450
Email: mn23z@nih.gov

Christopher Myers
Grants Management Branch
National Institute of Child Health and Human Development
6100 Executive Blvd., Room 8A17H, MSC 7510
Bethesda, MD 20892-7510
Telephone:(301) 435-6996
FAX:(301) 402-0915
Email: cm143g@nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at

http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

APPLICATION RECEIPT DATES: Applications submitted in response to this program announcement will be accepted at the standard application deadlines, which are available at http://grants.nih.gov/grants/dates.htm. Application deadlines are also indicated in the PHS 398 application kit.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS: Applications requesting up to $250,000 per year in direct costs must be submitted in a modular grant format. The modular grant format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in $25,000 modules. Section C of the research grant application instructions for the PHS 398 (rev. 5/2001) at http://grants.nih.gov/grants/funding/phs398/phs398.html includes step-by-step guidance for preparing modular grants. Additional information on modular grants is available at http://grants.nih.gov/grants/funding/modular/modular.htm.

SPECIFIC INSTRUCTIONS FOR APPLICATIONS REQUESTING $500,000 OR MORE PER YEAR:
Applications requesting $500,000 or more in direct costs for any year must include a cover letter identifying the NIH staff member within one of NIH institutes or centers who has agreed to accept assignment of the application.

Applicants requesting more than $500,000 must carry out the following steps:

1)Contact the IC program staff at least 6 weeks before submitting the application, i.e., as you are developing plans for the study;

2) Obtain agreement from the IC staff that the IC will accept your application for consideration for award; and,

3) Identify, in a cover letter sent with the application, the staff member and IC who agreed to accept assignment of the application.

This policy applies to all investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended or revised version of these grant application types.

Additional information on this policy is available in the NIH Guide for Grants and Contracts, October 19, 2001 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

APPLICATION PROCESSING: Applications must be received by or mailed on or before the receipt dates described at http://grants.nih.gov/grants/funding/submissionschedule.htm. The CSR will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such application must include an Introduction addressing the previous critique.

PEER REVIEW PROCESS

Applications submitted for this PA will be assigned on the basis of established PHS referral guidelines. An appropriate scientific review group convened in accordance with the standard NIH peer review procedures (http://www.csr.nih.gov/refrev.htm) will evaluate applications for scientific and technical merit.

As part of the initial merit review, all applications will:

o Receive a written critique
o Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score
o Receive a second level review by the appropriate national advisory council or board

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of your application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals:

o Significance
o Approach
o Innovation
o Investigator
o Environment

The scientific review group will address and consider each of these criteria in assigning your application's overall score, weighting them as appropriate for each application. Your application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, you may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

(1) SIGNIFICANCE: Does your study address an important problem? If the aims of your application are achieved, how do they advance scientific knowledge? What will be the effect of these studies on the concepts or methods that drive this field?

(2) APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Do you acknowledge potential problem areas and consider alternative tactics?

(3) INNOVATION: Does your project employ novel concepts, approaches or methods? Are the aims original and innovative? Does your project challenge existing paradigms or develop new methodologies or technologies?

(4) INVESTIGATOR: Are you appropriately trained and well suited to carry out this work? Is the work proposed appropriate to your experience level as the principal investigator and to that of other researchers (if any)?

(5) ENVIRONMENT: Does the scientific environment in which your work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, your application will also be reviewed with respect to the following:

PROTECTIONS: The adequacy of the proposed protection for humans, animals, or the environment, to the extent they may be adversely affected by the project proposed in the application.

INCLUSION: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria included in the section on Federal Citations, below)

DATA SHARING: The adequacy of the proposed plan to share data, if applicable.

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

AWARD CRITERIA

Applications submitted in response to a PA will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

o Scientific merit of the proposed project as determined by peer review
o Availability of funds
o Relevance to program priorities

REQUIRED FEDERAL CITATIONS

MONITORING PLAN AND DATA SAFETY AND MONITORING BOARD: Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

Specific information about NIAMS support of clinical research can be found at: http://www.niams.nih.gov/rtac/clinical/index.htm.

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.
The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:
The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at http://grants.nih.gov/grants/funding/children/children.htm.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at http://grants.nih.gov/grants/stem_cells.htm and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov). It is the responsibility of the applicant to provide the official NIH identifier(s)for the hESC line(s)to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance No. 93.846 and 93.929, and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies described at http://grants.nih.gov/grants/policy/policy.htm and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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